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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,313	10/15/2001	Kristina Marie Burow	36-001100US	4969

22798 7590 04/14/2005

QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.
P O BOX 458
ALAMEDA, CA 94501

EXAMINER

SODERQUIST, ARLEN

ART UNIT PAPER NUMBER

1743

DATE MAILED: 04/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

12 8 m

Office Action Summary	Application No.	Applicant(s)	
	09/981,313	BUROW ET AL.	
	Examiner	Art Unit	
	Arlen Soderquist	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2005 and 22 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-89 is/are pending in the application.
- 4a) Of the above claim(s) 75-89 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 15 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. The disclosure is objected to because of the following informalities: the instant specification has included on page 1 a copyright authorization, however the copyright work notice "©" does not appear in the specification as required to identify that which is copyrighted work. Thus applicant should either remove the copyright authorization or place one or more copyright work notices at appropriate places in the specification to properly identify the previously copyrighted work (see MPEP 608.01(v)).

Appropriate correction is required.

2. Claims 1-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1 it is not clear if the language of subparagraph (d) as amended requires the transfer station of subparagraph (c) to at least transport the sample holders (claim 19), to be capable of both transferring samples and transporting sample holders between the work perimeters, requires a control means of some sort for the transfer stations to cause the sample holders to be transported (claim 57?) or is non-limiting to the structure of the other elements of claim 1. The answer to this question will also have a direct bearing on at least claims 15, 19-20 and 68. If the transfer devices are required to at least transfer the sample holders between work perimeters, it is not clear if each of these claims is further limiting because the scope of the transfer stations of claim 1 require the sample holders to be transported between work perimeters (claim 19) and therefore preclude a transfer station that is only a fluid transfer device (claims 20,68) or allows different sample holders to remain within specified work perimeters (claim 15). Since claims 15, 19-20 and 68 are present, examiner will treat the language of subparagraph (d) in claim 1 as non-limiting on the other elements of claim 1 for examination purposes. It is also not clear if the transfer station of subparagraph (c) of claim 1 constitutes the at least one device associated with each of the work perimeters as set forth on subparagraph (b) (see claims 23-25) or is required to be in addition to the at least one device of subparagraph (b). Because of claim 23, examiner will treat the transfer station as capable of functioning as the at least one device of subparagraph (b) for examining purposes. In claim 9, it is not clear if the assay holders are distinct from the sample holders of claim 2 or if the sample holder of claim 2 can also be the assay holder of claim 9. For examining purposes examiner will treat the sample holders of claim 2 as capable of functioning as the assay holders of claim 9. Claim 15 appears to redefine the

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work perimeter of claim 1 as the sample holders which is not consistent with claim 1. For examining purposes, claim 15 will be treated by examiner as the sample holders in a first work perimeter comprise the 384-well plates and the sample holders of a second perimeter comprise 1536-well plates. With claim 15 it is also not clear if the first and second work perimeters are those of claim 1 that have a transfer station associated therewith or are different from the first and second work perimeters and not required to have a transfer station associated therebetween.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claims 1-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amano (US 4,835,707 in view of Kedar (US 6,323,035), Ishibashi (US 5,087,423) and Stylli (US 5,985,214). In the patent Amano teaches an automatic analysis method of and apparatus for the full automation of an enzyme reaction analysis from the pretreatment step of the reaction to the data processing step, wherein the operation of the pretreatment step is arranged to be sequentially performed on many samples with full automation by the use of robots (the robot shown is a rotational robot, 20) and computers to improve savings efficiency and measurement accuracy. Also, the pretreatment steps of weighing samples in many sample tubes, adding the given amount of solvent corresponding to the weighing value and placing the samples into the dissolution vessel to dissolve the sample in the solvent are adapted to be sequentially performed with full automation with the use of the robot, computer and electronic balance. Furthermore, the filtration, concentration and the injecting operations into the HPLC are automatically

performed. The automatic apparatuses are coupled to each other so that the filtration, concentration, injecting operations are allowed to be sequentially performed with full automation using an on-line system. The summary of the invention describes several stations for treating the samples and two separate rotation robots to move the samples and treat them. In particular the device includes a weighing and dissolution apparatus, grasping a sample tube retained in a rack with a chuck provided on a movable arm of a first automatic robot for weighing the sample with an electronic balance, adding a predetermined amount of solvent to the sample in accordance with the weighing value of the sample, placing the sample tube into the dissolution vessel to dissolve the sample after the addition of solvent, moving the sample tube containing the dissolved sample onto a rack for dilution provided on a dilution and reacting apparatus; with the dilution and reacting apparatus, grasping a nozzle of a dilution dispenser, a sampling pipetter or an enzyme reaction mixture dispenser with the chuck of a second automatic robot to move the nozzle into the sample tube retained on the dilution rack or the reaction tube retained on a rack in an incubator, adding the diluted solution from the dilution dispenser into the sample tube located in the dilution rack to perform the diluting operation by a given amount, taking a sampling of the diluted solution from the sample tube with the sampling pipetter to inject it into the reaction tube, sequentially injecting enzymes and factors necessary for the enzyme reaction into the reaction tube at intervals of a given time, grasping the reaction tube with the second robot to move it into the preservation vessel after the reaction; grasping the reaction tube retained in the preservation vessel with the second robot to place it in the position of a reaction mixture sampling needle disposed in a filtration, concentration and analysis apparatus, filtering the reaction mixture through a filtration unit after the sampling operation of reaction mixture with the sampling needle, feeding eluate into a concentration column after adsorption of the filtrate onto the concentration column, automatically injecting it into an analysis column for analysis by a HPLC, processing the obtained data by a data processing apparatus; and automatically controlling the operations of the first and second robots in accordance with a program input into a computer to automatically perform all of the operations from weighing to analysis. Amano does not teach a plurality of modules, multi-well plates as sample holders or non-sequential treatment of the samples.

In the patent Kedar teaches systems and methods for handling multi-well plates. In one example a system is provided with a rotational robot having a base member and at least one arm. The arm includes a grasping mechanism which is adapted to grasp the plate. Further, the grasping mechanism is configured to receive the plate in a repeatable and known location such that the location of each well relative to the grasping mechanism is known by the robot. The invention relates generally to the field of device handling and manipulation, and particularly to the handling and manipulation of multi-well plates. In one particular aspect, the invention provides for the transport of multi-well plates to precise and known locations at various processing or evaluation stations. The use of multi-well plates to facilitate the performance of various chemical and biological procedures has become widely accepted. Such multi-well plates are typically rectangular in geometry and have a two dimensional array of wells (8 by 12 or 96 wells). To accommodate the performance of various procedures, the wells of such plates are configured to receive various chemicals or substances. One common procedure is the performance of assays where various chemicals or substances are introduced into the wells and any reactions are evaluated. One type of assay evaluation may proceed by placing the plate above a camera to detect an emitted signal from the wells. When using multi-well plates, it is often desirable to efficiently deliver and/or remove various chemicals or substances into or from the wells. This often requires the plate to be moved to various pieces of processing equipment for filling or removal. Further, the plates may also need to be transported to evaluation equipment for detection or other evaluation. When introducing or removing fluids or substances into or from the wells, and when evaluating the substances within the wells, the wells typically need to be aligned with distal tips, detection devices and the like. However, since various pieces of equipment may be needed to complete a procedure, each time the plate is moved to a different piece of equipment, the plate will need to be properly oriented according to the specifications of the given piece of equipment. For example, many types of fluid delivery equipment include a stage on which the plate is placed. Often a robot is employed to grasp the plate and move the plate to the stage. However, such robots typically have a pair of grasping fingers that grasp the plate in an arbitrary manner and then place the plate on the stage. Once on the stage and removed from the robot, the dispensing tips will need to be aligned with the wells in the plate. Such a system is often burdensome and time consuming. Moreover, as it becomes more

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desirable to increase the numbers of wells in the plate while reducing their size, it becomes more difficult to precisely align the wells with various pieces of equipment. For example, many types of filling equipment are provided with 96 dispensing tips. If an 864 well plate is placed on a stage which can move only in the vertical direction, it is difficult, if not impossible, for the 96 dispensing tips to fill all of the 864 wells while the plate remains fixed on the stage. Hence, it would be desirable to provide systems, devices and methods to facilitate the transport of multi-well plates between various pieces of equipment in a manner such that the wells may be efficiently accessed or evaluated. The Kedar apparatus is taught as fulfilling this desire.

In the patent Ishibashi teaches an automatic analyzing device having a plurality of analyzing modules, a plurality of analyzing routes and at least one bypass route bypassing at least one analyzing module. Each analyzing module is capable of analyzing samples with respect to one or more items, and samples successively supplied from the introduction sides of the modules are selectively delivered into each module in accordance with the possible analyzing items of each module and the analyzing items of the samples to be analyzed. The sample cup can pass the module via a bypass or can be returned to the introduction side of the module via a bypass, in accordance with the items to be analyzed, the effective distribution of the sample cups can be performed. Column 1, lines 19-45 discuss known analyzing apparatus in which analyzing modules ranging from two to eight are serially arranged, and sample cups each containing sample liquids to be analyzed are successively conveyed to the modules one by one via only one route. Necessary amounts of the samples are picked up and delivered into reaction vessels in the modules according to the analyzing items of each sample that are to be analyzed by each module. Although it is not necessary to analyze all items for each sample, all samples have to be successively fed to each of the analyzing modules. Since the each module can analyze from four to twelve items, it is possible to analyze 20-30 items in the automatic analyzing apparatus as a whole. Generally, not all samples require the same analyzing items. In general, a sample requires only 50-60% of all possible analyzing items of the apparatus. In other words, 40-50% of the analysis capacity is not being used for each respective sample. Lines 47-57 explain that this is a disadvantage since it increases the processing/analysis time. To solve this problem Ishibashi teaches arranging the analysis modules in a parallel or serial manner and transferring the sample cups to the module that performs the required analysis/analyses without respect to the

order in which the sample cups were supplied with sample (see column 2, lines 11-57). In other words the samples are sent directly to the analysis modules that are required by providing a bypass path around analysis modules that are unnecessary. Lines 58-60 teach that this allows the apparatus to operate all of the analyzing modules efficiently without waste of time.

In the patent Stylli teaches systems and methods for rapidly identifying useful chemicals in liquid systems and uses automated and integratable workstations for identifying chemicals having useful activity. The present invention is also directed to chemical entities and information (e.g., chemical or biological activities of chemicals) generated or discovered by operation of workstations of the present invention. The present invention includes automated workstations that are programmably controlled to minimize processing times at each workstation and that can be integrated to minimize the processing time of the liquid samples from the start to finish of the process. Systems and methods for rapidly identifying chemicals with biological activity in samples, especially small liquid samples, can benefit a number of different fields. For instance, the agrochemical, pharmaceutical, and cosmetic fields all have applications where large numbers of liquid samples containing chemicals are processed. Currently, many such fields use various strategies to reduce processing times, such as simplified chemistry, semi-automation and robotics. While such strategies may improve the processing time for a particular type of liquid sample, process step or chemical reaction, such methods or apparatuses can seldom integrate the entire process, especially the generation or detection of chemical events in small volumes. Such apparatus are also often limited in their application, since many of them are designed for, and dedicated to, a particular type of liquid sample or chemical reaction. In most processes involving liquid samples, as the complexity of the liquid sample processing increases the process time per sample increases. Although, some very simple chemical reactions or liquid processing methods can achieve extremely high throughput rates, such as in the manufacturing of containerized liquids, complicated processing of liquids is typically several orders of magnitude slower. In some instances, the processing of liquid samples, such as in pharmaceutical arts, which usually demands complicated liquid processing for drug discovery, can obtain throughput rates of approximately 3,000 samples per day. This type of processing in general, however, uses liquid sample volumes on the order of 100 to 200 microliters, which often requires relatively large amounts of exotic and expensive reagents, and does not typically incorporate automated access

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to large stores of liquid reagents. Consequently, there is a need to provide components, systems and methods for rapidly processing liquid samples at high throughput rates, particularly liquid samples of microliter volumes, one to ten microliters, to identify chemicals with useful activity. Columns 2-3 teach several modules for the Stylli apparatus. Columns 3-5 provide several definitions of which adaptive routing, daughter plate and parallel processing are relevant to the ability to increase the throughput of the device. Column 18, lines 33-50 teach various rates of throughput going up to 10 million wells processed in a day. The following paragraph explains how parallel processing can be used to increase the throughput.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide several modules as taught by Stylli or Ishibashi and incorporate parallel processing of Stylli or the non sequential sample transport of Ishibashi into the Amano apparatus because of the ability increase the throughput as taught by Stylli and to operate each analysis/processing module efficiently and reduce wasted time due to the successive treatment of the samples as taught by Ishibashi. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the multi-well plates of Stylli or Kedar along with the plate grasping mechanism of Kedar into the Amano device because of the ability to increase throughput or facilitate the efficient processing of samples as taught by Kedar and Stylli.

5. Applicant's arguments filed January 14, 2005 have been fully considered but they are not persuasive. First relative to the copyright authorization notice, after looking into the explanation of the presence of copyrighted material in an application examiner has determined that the specification is lacking any indication of copyrighted subject matter in the specification. The copyright authorization statement does not provide applicant any copyright protection. It simply alerts one to the fact that applicant has obtained permission from a copyright holder to incorporate copyrighted material into an application. Applicant is then required to appropriately mark the copyrighted material using the copyright work notice, "©". If the instant application does not contain copyrighted material, the authorization statement should be removed. If there is copyrighted material in the specification, it should be appropriately marked (see MPEP 608.01(v)).

Relative to the remaining art rejection examiner points out that applicant appears to have not properly read the rejection. It is the Amano patent in view of the Kedar patent, the Ishibashi

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patent and the Stylli patent rather than as applicant has treated the rejection the Amano patent in view of the Kedar patent, the Ishibashi patent or the Stylli patent. While the combination of the Amano reference with each of the secondary references individually as applicant has argued does not meet the all claim limitations of claim 1, the combined teachings of the references would have motivated one of ordinary skill in the art to change the teachings of the Amano reference to meet the instant claim limitations. In this respect applicant is directed to the fact that the Court has held that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference.... Rather, the test is what the combined teachings of those references would have suggested to those of ordinary skill in the art. In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). See also In re Sneed, 710 F.2d 1544, 1550, 218 USPQ 385, 389 (Fed. Cir. 1983), it is not necessary that the inventions of the references be physically combinable to render obvious the invention under review. In this respect that Kedar and Stylli references clearly show the advantages in terms of throughput when using multiwell plates rather than single tubes to contain samples. Additionally the Ishibashi and Stylli reference show that advantages of multiple processing stations that the sample holders are transported between in terms of sample throughput.

Relative to the new clarity issues, they are a result of the amendments to claim 1.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (571) 272-1265.

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The examiner's schedule is variable between the hours of about 6:30 AM to about 5:00 PM on Monday through Thursday and alternate Fridays.

A general phone number for the organization to which this application is assigned is (571) 272-1700. The fax phone number to file official papers for this application or proceeding is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Arlen Soderquist", with a stylized flourish at the end.

April 12, 2005

**ARLEN SODERQUIST
PRIMARY EXAMINER**